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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,852	07/10/2000	Victor N. Krasnykh	D6070CIP	9473

7590

09/23/2002

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/612,852

Applicant(s)

KRASNYKH ET AL.

Examiner

Brian Whiteman

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 August 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): The double patenting rejection for claims 1,2,5,6,8,12.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-6 and 8-15.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See Continuation Sheet


DAVE T. NGUYEN
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: The applicants have not provided new evidence or facts to overcome the outstanding rejections set forth in paper nos. 3 and 6, the applicants only restate the traversal set forth in paper no. 5. As stated in paper no. 6, applicants were enabled for an adenovirus comprising a fiber replacement protein wherein the protein is T4 bacteriophage fibrin protein which confers a novel tropism and maintains trimerization. However, in the response to the Non-Final, applicants cancelled the claim (claim 7) that corresponds to the scope of enablement. As stated in paper no. 6, the claimed invention is not enabled in view of the breadth of the claims for the genus of fiber replacement protein without an undue amount of experimentation because it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from a specific fiber replacement protein (T4 fibrin protein) to any other artificial fiber protein that will provide trimerization and other limitations encompassed by the claims for the reasons set forth in paper nos. 3 and 6 encompassing the lack of guidance provided by the as-filed specification and the art of record (Wickham). With respect to the applicants' traversal (See pages 4-5) that the modification of Wickham is distinct from the modification disclosed by the Applicants' specification, the traversal is acknowledged and is not found persuasive. Wickham teaches modification of a part of the fiber protein (page 8223), which would encompass the same problems associated with changing replacing the whole trimeric fiber shaft with another trimeric protein motif. Wickham teaches the unpredictability of altering natural tropism due to the inability of the chimeric protein to provide trimerization, which is considered an essential part of the applicants' claimed product. Therefore, in view of the lack of sufficient guidance for a representative number of fiber replacement proteins with the claimed characteristics and in view of the art of record, it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from producing a modified adenoviral vector with a T4 fibrin protein to the genus of adenoviral vectors with a claimed fiber replacement proteins.

With respect to the only intended (therapeutic method of gene therapy) use of the claimed invention, the claimed invention is not enabled for the reasons set forth in paper nos. 3 and 6. More specifically, the as-filed specification does not provide sufficient guidance for one skilled in the art to use the claimed product in any method of gene therapy because of the unpredictability of gene therapy (See Verma and Eck). In addition, in view of the unpredictability of gene therapy and the lack of working examples provided by the as-filed specification, it would take one skilled in the art an undue amount of experimentation to reasonably extrapolate from making a novel adenoviral vector to using the vector in any therapeutic method of gene therapy because of the art of record and the as-filed specification fails to provide sufficient guidance for what route is required for each distinct therapeutic gene; what amount of in vivo protein expression is required for one skilled in the art to observe a therapeutic response using said vector; how to overcome the host's immune system; how to target specific cells; how to overcome transient gene expression; and how to supply a sufficient amount of vector to each cell to ensure a therapeutic expression of said gene. In addition, the as-filed specification lacks sufficient guidance for how one skilled in the art would be able to overcome the unpredictability of gene therapy in further view of the lower infection level of the species (Ad5LucFF/6H) taught in the as-filed specification compared to a wild-type adenovirus vector (See page 39).

Continuation of 10. Other: The rejections for claims 1-6 and 8-15 under 112 first paragraph remain for the reasons set forth above and in view of the rejection set forth in paper nos. 3 and 6.

Note: The examiner of the instant application has changed. Please direct any responses to Brian Whiteman, 1635.

In the specification under cross reference, applicants should update the status of application 09/250,580 since it is now a patent.

A 948 is submitted with this advisory action, applicants are required to reply to the PTO948 in response to this action or the response will be considered non-responsive. See 37 CFR 1.121(d).



DAVE T. NGUYEN
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.